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Party	Defendant Meridian Bioscience, Inc.
Correspondence Address	J MICHAEL HURST KEATING MUETHING & KLEKAMP 1 E 4TH ST, STE 1400 CINCINNATI, OH 45202 3752 UNITED STATES mhurst@kmklaw.com, trademarks@kmklaw.com
Submission	Testimony For Defendant
Filer's Name	J. Michael Hurst
Filer's e-mail	mhurst@kmklaw.com
Signature	/j. michael hurst/
Date	03/19/2015
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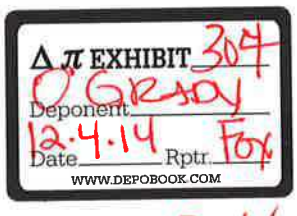
Exhibit 304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Deponent
12.4.14
Date
Rptr. Fox
WWW.DEPOBOOK.COM

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Diagnostics Portfolio Management Plan

July 20, 2009

Marketing Team Member – Mickie Henshall
Finance Team Member – Mike Poirier
Sustaining Team Member – Tom Rosso
Production Team Member – Paul Kitabjian
Development Team Member – John Moon
Dx Development Team Member – Joanne Yeakley
Executive Advisor – Greg Heath

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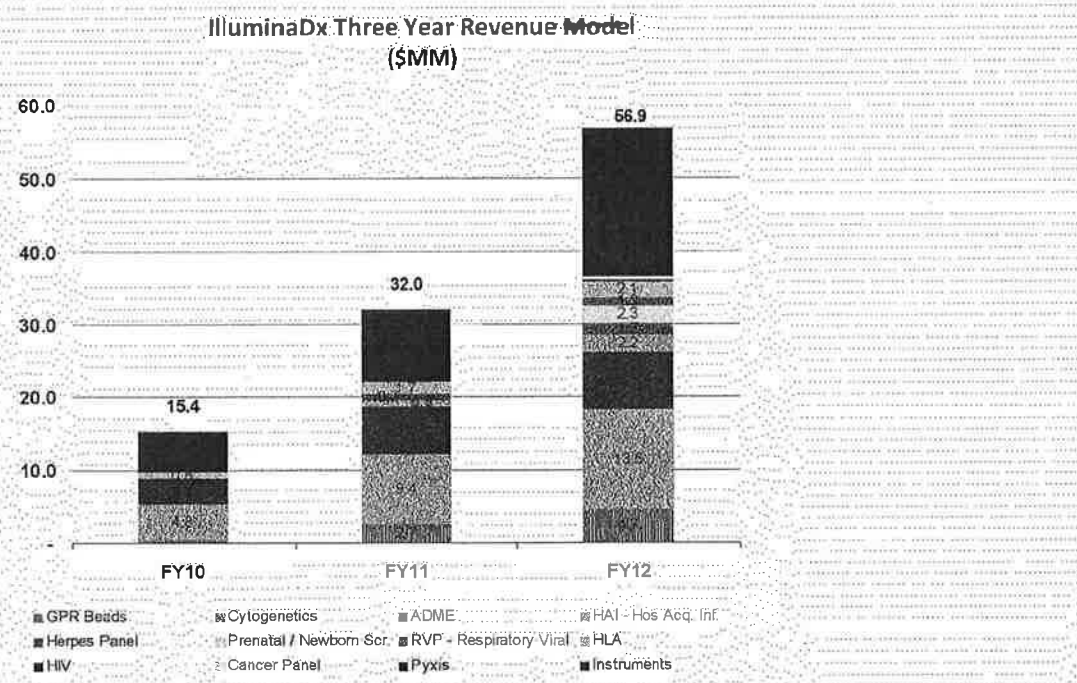
Executive Summary

With a broad portfolio of leading edge technologies and products, Illumina has become a leader in the Life Sciences market, maintaining impressive growth over the past eight years. It is estimated that by 2010, Illumina's market share will near 40%. In order to sustain long term growth, Illumina will need to access new markets and broaden its customer base. With a projected size of $4.3 billion in 2009 and growing at a rate of 16%, the Molecular Diagnostic Market offers a compelling segment to leverage Illumina's technologies.

In 2008, Illumina's diagnostic strategy was discussed in a series of executive meetings, synthesized into a three part plan, then presented to and approved by the Board of Directors on July 24, 2008. This portfolio management plan is built from the approved strategy, with supplemental development projects to ensure competitive advantage within the diagnostic market space.

Focusing internal efforts on: 1). Building a large install base with test menu and tools, 2). Developing a competitive diagnostic sequencing service, and 3). Discovering proprietary biomarkers for cancer, the plan establishes an installed base of instruments in clinical labs and reasonable growth over the next three years with low risk test panels, and the foundations for longer term success towards our goal of being a leader in translational oncology.



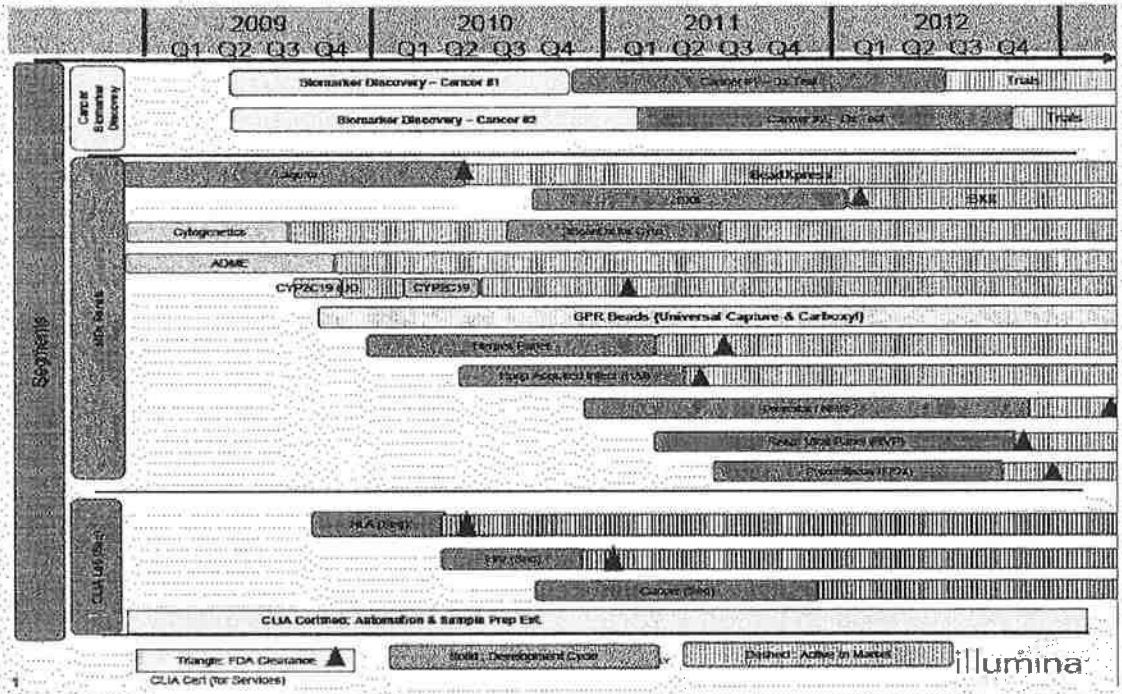
Recognizing molecular diagnostics will be a major philosophical shift to Illumina's current product development and manufacturing practices, the resources and key dependencies outlined in this plan are necessary to ensure successful commercialization. The performance requirements, stringency, and documentation required in diagnostics will translate to longer development time and costs than the development of research use only products. Without leveraging an acquisition strategy, comparable companies have typically shown of span of 8 to 10 years before establishing a successful business in molecular diagnostics. The plan assumes that the BeadXpress System and VeraCode beads will be FDA cleared in early 2010, and that Illumina shall have manufacturing under QSR with a complete CAPA system in place. This plan summarizes the three year pipeline from 2010 to 2012 only.

Product Development Pipeline

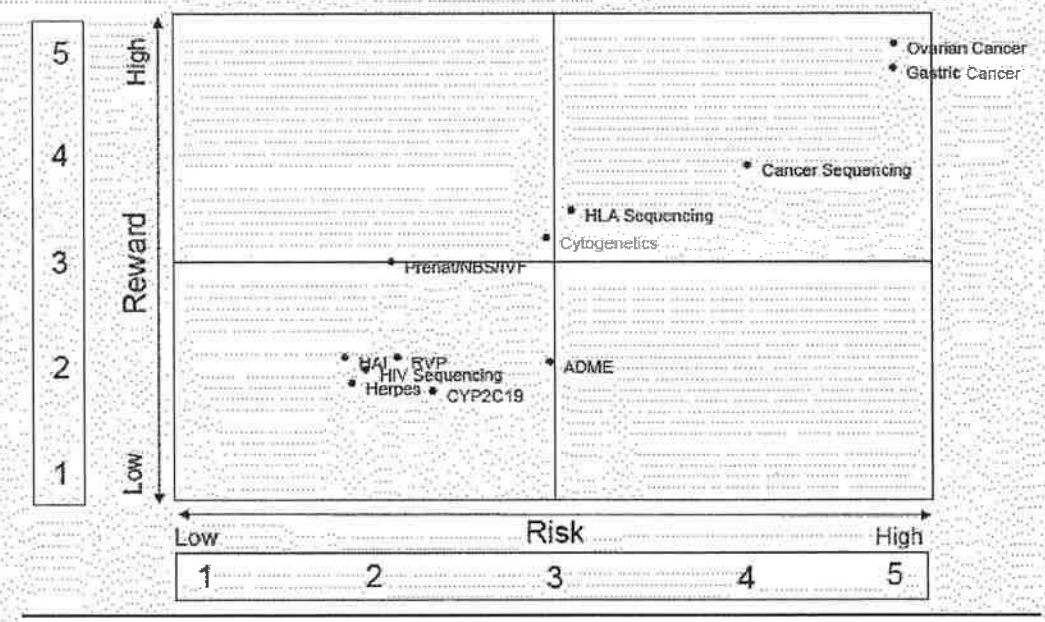
Pipeline Overview

The diagnostic product development pipeline can be divided into three main sections: 1). Cancer Biomarker Discovery, 2). Molecular Diagnostic Panels, and 3). Clinical Sequencing Service. The three part approach serves to leverage Illumina's key technologies, provide a balanced risk/reward model, and establish a large install base for the downstream proprietary cancer tests.

Product Pipeline



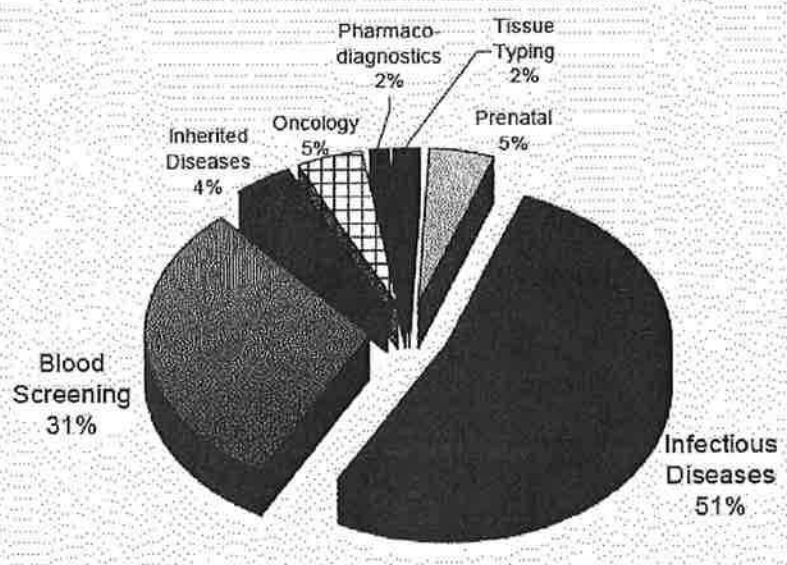
Risk/Reward Model



By developing tests outlined in the pipeline, Illumina shall address multiple segments within the total molecular diagnostic testing market, facilitating a larger install base for the BeadXpress system. While

some of the sectors appear relatively small, they account for the fastest growing segments in diagnostics with currently unmet laboratory needs.

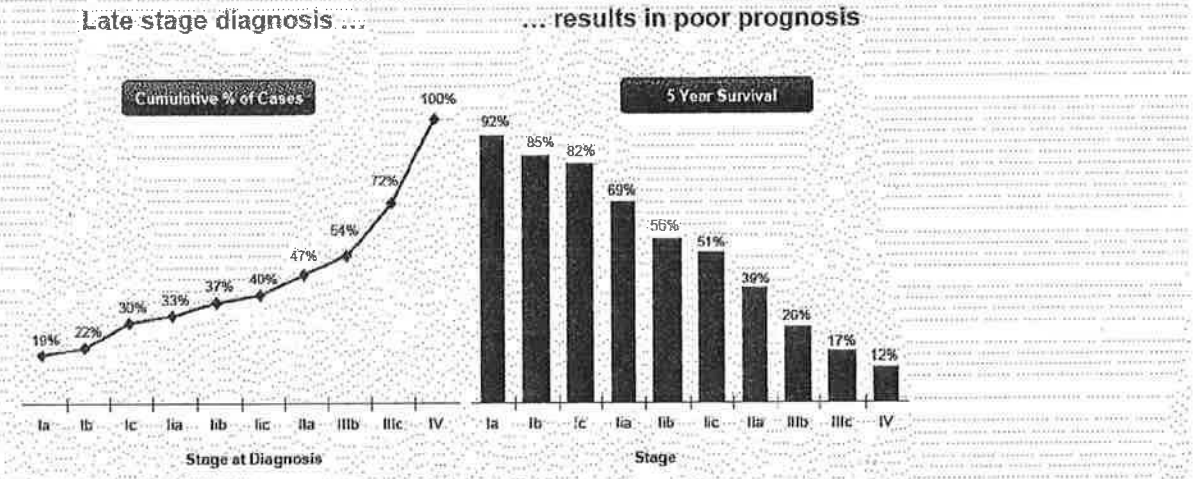
2008 Molecular Testing Market Share by Type



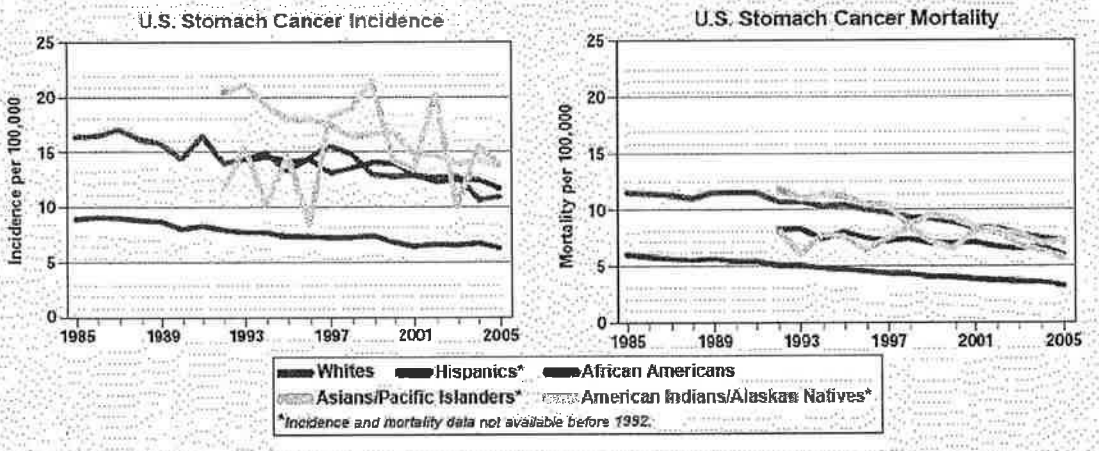
Cancer Biomarker Discovery Program

The primary component of Illumina's Diagnostic Strategy is to be a leader in translational oncology. Leveraging the Genome Analyzer sequencing technology and downstream array platforms, Illumina is one of the few companies equipped to rapidly and affordably bridge biomarker discovery to validation and diagnostics. Illumina will focus on biomarkers for early detection of cancer, beginning with:

- Ovarian Cancer – The fifth leading cause of cancer mortality among women, with 15,520 deaths reported in 2008 (US only). Difficult to diagnose due to non-specific symptoms, less than 40% of women diagnosed with ovarian cancer are cured. Recent studies have shown, however, that early detection of ovarian cancer leads to marked improvement in prognosis. It is estimated that more than $2.2 billion[‡] is spent on the treatment of ovarian cancer per year in the U.S.



- Gastric Cancer – Also referred to as stomach cancer, it is the second leading cause of cancer related deaths in the world. Over 760,000 cases are diagnosed worldwide and more than 24,000 cases are diagnosed in the United States each year as reported by the National Cancer Institute. While incidence is highest in Japan, South America, Eastern Europe, and parts of the Middle East, the incidence of proximal gastric cancer (upper stomach) has been increasing in the U.S. due primarily as a result of the prevalence of obesity and gastroesophageal reflux disease (GERD). Gastric cancer spreads easily to other major organs, which makes early detection and treatment critical.



Molecular Oncology Market

Routine cancer diagnostics are currently comprised of immunoassays and analysis of biopsied tissues using immunohistochemical stains and in-situ hybridization. Molecular tests in oncology have not yet gained significant market penetration, representing just 15% of the total market for routine cancer diagnostics. However, with new tools and biomarkers appearing in the market, molecular methods are beginning to make their way into cancer management. Although recent market research reports estimate the molecular oncology market at $150M with 15% annual growth to exceed $300M by 2012, it is more likely that the molecular oncology market is closer to $400M when including the revenues of

companies such as Genomic Health and Myriad Genetics who offer their proprietary cancer tests as a service. Genomic Health achieved revenues of $100M in 2008, while Myriad Genetics achieved sales exceeding $145M.

Competitive Advantage

With a discovery program that is focused on comprehensive genetic analysis, including whole transcriptome and methylome analysis, Illumina has the potential to develop a highly specific diagnostic test that addresses the complexities inherent in cancer. With the cost advantages of Illumina's Genome Analyzer, Illumina shall be able to undertake this discovery program at a fraction of the time and cost of other entities. Relative to earlier cancer diagnostics in the market, Illumina shall have a rapid path to commercialization through an initial offering as a service by the CLIA lab, which shall facilitate data generation for a likely PMA submission to the FDA.

Forecast Projections

Based upon the length of time required for each phase of the discovery program, the platform team does not anticipate commercialization until after 2012. If the discovery program proves to be successful for at least one of the cancer projects (demonstrating strong clinical utility), we can anticipate growth with market uptake and reimbursement along the lines of what Genomic Health experienced. However, it should be recognized that this will initially be run through ILMN's CLIA services, which will base the price per test at an average of $3,000 (Genomic Health's OncoType Dx is $3,500 per sample; Myriad's BRCA 1 is $3,000):

	2004	2005	2006	2007
OncoType Dx # of Tests	550	7,000	14,500	24,000
Genomic Health Revenues	$1.9M	$24M	$51M	$84M

ILMN Cancer Dx	2013	2014	2015
# Samples	400	5,000	10,000
Revenue	$1.2M	$15M	$30M
ASP	$3,000	$3,000	$3,000
Est. GM%			

Key Dependencies

- Securing of all clinical samples necessary for both discovery and validation efforts
- Bio-informatics for analysis of data generated from sequencing
- Discovery of proprietary and clinically relevant biomarkers
- Published utilization of test as part of medical practice and reimbursement

Pharmacogenomics – ADME Core & CYP2C19

The VeraCode ADME Core will be targeted to Pharma companies performing pharmacogenetic analysis in association with drug trials. Follow-on products are likely to evolve from use of VeraCode ADME Core that will be targeted to the clinical diagnostic market, the first of which will be a panel of CYP2C19 markers associated with the metabolism of Plavix®/ clopidogrel. Other follow on opportunities include the gene CYP2D6 with diverse drug associations, CYP2C9/VKORC1 associated with warfarin metabolism,

and UGT1A1 associated with irrenotecan metabolism. Other associations are likely to arise as pharmas screen new drugs using the ADME core product. The ADME core panel shall include:

- ABCB1 (4)
- ABCC2 (6)
- ABCG2 (2)
- CYP1A1 (7)
- CYP1A2 (4)
- CYP2A6 (13)
- CYP2B6 (5)
- CYP2C19 (9)
- CYP2C8 (7)
- CYP2C9 (13)
- CYP2D6 (24)
- CYP2E1 (1)
- CYP3A4 (3)
- CYP3A5 (5)
- DPYD 96)
- GSTM1 (3)
- GSTP1 (2)
- GSTT1 (1)
- NAT1 (7)
- NAT2 (8)
- SLC15A2 (4)
- SLC22A (10)
- SLC22A2 (5)
- SLC22A6 (1)
- SLC01B1 (10)
- SLC02B1 (1)
- SLC01B3 (2)
- SULT1A1 (5)
- TPMT (6)
- UGT1A1 (6)
- UGT2B15 (1)
- UGT2B17 (1)
- UGT2B7 (2)
- VKORC1 (1)

Market Summary

The Pharmacodiagnostics Market earned $50M in 2007 and is predicted to reach $200M by 2010, 32% CAGR (Kalorama 2008). According to Parexel's BioPharmaceutical report, pharmacogemomics were used in 43% of drug clinical trials in 2004 and earned an estimated $100M in 2004, 78% CAGR from 2000 to 2004. They estimate use of pharmacogenomics assays to select participants estimated to respond to the drug in clinical trial will reduce the traditional 10 to 12 year trial duration 30% to 40% down to 3 to 5 years. The top 10 Pharmas have 89 to 202 drugs (1244 total) in the development pipeline as of March 2007 and 417 drugs are in phase 1 trials, 404 are in phase 2, and 247 are on phase 3 trials.

The estimated cost of taking a drug through development is >$800M, a major driver of Phamas to adopt ADME gene analysis to identify safety concerns earlier in the development process and trace adverse drug reactions back to specific mutations. They will also use the ADME Core panel to understand genetics of differential metabolism, especially in phase 2 trials, driving dosing considerations and to distinguish responders / non-responders in phase 2 & 3 trials (20%) to predict likelihood of clinical success.

As the FDA comes to expect pharmacogenomic data with NDAs, the adoption of products like the VeraCode ADME Core will grow. In recent months the FDA updated several drugs referencing pharmacogenetic testing including the package insert for Plavix/clopidogrel referencing efficacy association with CYP2C19 phenotype, and updates to the indication and usage of Amgen's Vectibix and ImClone.

Competitive Advantage

Key differentiators of VeraCode ADME Core include a precise focus on the content that has been shown through peer reviewed publications to have clinical utility. The chemistry used in the assay adds an additional layer of specificity, ensuring the appropriate allele is targeted in genes that have homologous regions. Robust internal controls providing g sample bar-coding and detecting user error add to the overall quality of this application developed under design control and provided with a specific software module. The savings in assay time, hands on time and overall assay costs make this product a clear strong competitor to the DMET assay.

Follow on products to ADME Core like a CYP2C19 assay will compete directly with low-plex molecular diagnostic platforms like Luminex, Autogenomics and Osmetech, but will leverage key advantages such as price, scalability, specificity, and precision.

ADME Competitive Summary

	VeraCode ADME Core	Affy DMET	Roche Amplichip	Luminex	Homebrew (Eg. Fluidigm)
Content	184 polym. All ADME Core	1996 polym. 90% ADME Core	27 polym in CYP 2D6 & 3 in 2C19	P450-2C19 (7) P450-2C9 (5) P450-2D6 (14) P450-2C9+VKORC1 (6)	Custom, No fixed ADME Panel in development
Performance	Target 100% conversion, >99% accuracy and call rate	99% accuracy, reportedly low call rate.	>99% call rate, >99% accuracy	>99% accuray and call rate	>99% call rate and accuracy
Software	"clinical" locked software with * allele conversion	RUO software with * allele conversion	IVD software with * allele conversion	IUO software	Custom
Price	$200/spl $1.36/SNP $160 volume discount	$350/spl (as low as $200) $.42/SNP	$200/spl $6.67/SNP	$35 to $50/spl $2 to $7/SNP	$ .11 per SNP with 96.96 array* (VC GGGT 96plex $.09 - $.11/SNP)
Workflow	32 samples <8 hours	48 samples 3 days	24 samples 1 day	24 samples /day	96 samples 3-4 hours
HOT	2 hrs	11 hours	~3-4 hrs	2+ hrs	< 1 hr
Install Base	140+ with Asia Pacific Placement	Limited service providers	8 labs perform test	>5835 with Asia Pacific Placement	96.96 newly launched product

Forecast Projections

ADME CORE	2010	2011	2012
# Samples	21K	47K	72K
Revenue	$3.6M	$6.5M	$8.0M
ASP	$170	$140	$112
Est. GM%	91%	91%	89%

CYP2C19	2010	2011	2012
# Samples	185K	190K	196K
Revenue	$2.8M	$2.9M	$2.9M
ASP	$15	$15	$15
Est. GM%	80%	80%	80%

Key Dependencies

- ADME Core must include as a minimum all of the DNA based biomarkers of enzyme activities considered as valid biomarkers (Huang et.al 2006).
- CYP2C19 adoption will rely largely on the results of trials demonstrating non-inferiority between clopidogrel and prasugrel driving an economic basis for testing 2C19 to maintain EMs on the generic drug clopidogrel. The baseline forecast assumes securing the Medco specific market for CYP2C19 testing programs (400 samples/ yr).
- Other follow on test will rely on the successful completion of ADME Core development

Herpes Panel

Illumina's Herpes Panel (or alternately – viral infections in transplant panel) shall be a multiplex molecular assay, detecting viruses and bacteria responsible for diseases that can be grouped into mononucleosis, viral meningitis, and infection of the newborn. The analytes in this panel are of highest risk to individuals that are immune suppressed, such as organ transplant and HIV patients, and shall include:

- Cytomegalovirus (CMV) – A member of the herpes virus family, CMV usually results in childhood as a mild infection similar to a typical cold. In immune suppressed individuals, CMV may result in more serious illness involving fever, pneumonia and other symptoms. In some rare instances, newborns may have significant illness involving nervous system damage, developmental disorders, and hearing loss. The March of Dimes estimates that each year, 27,000 pregnant women with primary CMV and have births that are at high risk for having newborns with congenital CMV.
- Epstein-Barr virus (EBV) – A member of the herpes virus family, the most common result of EBV is mononucleosis (mono). Methods for diagnosing mon include symptom analysis, a complete blood count, and an antibody test. Especially among children, a percentage of those tested for mono will have a negative mono test. A molecular EBV test can more accurately determine whether infection is due to EBV.
- Varicella zoster virus (VZV) – Primary VZV infection results in chickenpox, which on rare occasions may result in complications including encephalitis or pneumonia. Prior to vaccine implementation in 1995, approximately four million cases of varicella were estimated to occur annually in the U.S., including 11,000–13,500 hospitalizations and 100-150 deaths. Even after clinical symptoms of chickenpox have been resolved, VZV remains dormant in the nervous system of the infected person. In about 10 – 20% of cases, VZV reactivates later in life, producing a disease known as herpes zoster or "shingles". Serious complications include Postherpetic neuralgia, meningoencephalitis and encephalitis.

Market Summary

Although the viruses within this panel pose significant public health problems, these diseases are not reported to the U.S. CDC unless there is a major isolated outbreak requiring surveillance, so there is little published market data. In the Emmes 2008 Molecular Test Database, a database surveying approximately 1700 hospital, reference and public health labs, these tests are usually run separately (single analyte test), and most are performed by traditional culture and immunoassays. The majority of commercialized kits on the market are either immunoassay based or rapid tests.

Reagent Type Used (Commercial, ASR, Homebrew) by Analyte (as % of clinical lab respondents)

Virus	Commercial Kit (FDA cleared)	ASR	Homebrew
CMV	44%	31%	25%
EBV	31%	20%	49%
VZV	40%	20%	40%

**Emmes*

Among the panel, CMV is tested at the highest volume, with the largest number of tests run by large reference laboratories. With a multiplex assay, the available market will be a subset of the highest volume test (CMV in this case) as labs convert to multiplex methods to reduce the cost and labor associated with running several individual tests. The available market is estimated at 300,000 tests per year, growing at a rate of 8% per year.

Analyte Testing Volume by Bed Size of Hospital and All Non-Hospital Labs (Ref)

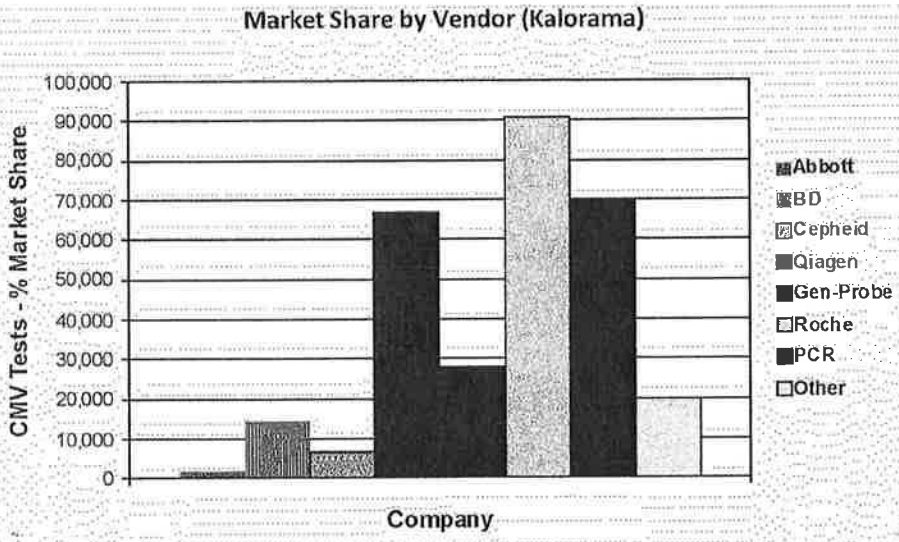
Analyte	1 - 199	200 - 299	300 - 499	500 - 1000	>1000	Ref Lab	Total
CMV	13,950	18,815	52,550	130,350	28,500	33,880	278,045

**Emmes, 2008 Database*

Competitive Advantage

Unlike the competitors listed above, Illumina shall enable clinical laboratories to reduce costs, increase throughput, reduce sample requirements, and minimize labor resources by commercializing a multiplex diagnostic panel, comprised of all three viral targets. As a comparison, the average price for testing a single analyte using a commercial kit is $15 - $20, depending on lab volume. A homebrew qPCR test can run from $7 - $12 per analyte. When adding each of the tests separately from the panel, a lab would have to spend anywhere from $21 to $60 per sample. By comparison, Illumina could provide the entire panel at an ASP of $40 per sample. With approximately 85% GM, there would be additional room for discounting of larger orders if necessary.

In addition to the value of multiplexing capabilities, the VeraCode technology will enable inclusion of internal assay controls and controls to trigger automatic calling thresholds and data analysis reports. For most clinical labs, moving away from immunoassay based tests to nucleic acid based tests will demonstrate significant improvements in sensitivity and specificity. Finally, this plan assumes that the assay shall benefit from the EraGen chemistry, enabling results within three hours and requiring less than 30 minutes of hands-on time. None of the major commercial leaders in this test segment have a multiplex panel, providing an opening for new technologies.



Forecast Projections

	2010	2011	2012
# Samples	n/a	18,000	49,000
Revenue	n/a	$0.72M	$1.7M
ASP	$40	$40	$35
Est. GM%		83%	80%

Key Dependencies

- Complete EraGen / ILMN agreement; enable development with EraCode modified bases. If this rapid assay chemistry is not available to ILMN, the Dx platform team believes that ILMN's infectious disease assays will need to be reconsidered as it would not demonstrate competitive advantage using ILMN's FastGG assay.
- R&D developers experienced in designing assays with viral targets
- Semi-quantitative data for CMV

Hospital Acquired Infections

Hospital acquired infections (HAIs), also known as "sepsis", are caused when infecting pathogens enter the blood stream. Surprisingly, in the U.S. it is the leading cause of death in non-coronary intensive care units, and the 10th most common cause of death overall (CDC). Illumina's HAI Panel shall interrogate the following analytes:

- Methicillin-resistant *Staphylococcus aureas* (MRSA) – The most virulent pathogen involved in HAI, accounts for 10% of all cases and is the most deadly of the hospital acquired pathogens. MRSA is the market driver for HAI testing.
- Methicillin-Sensitive Staphylococcus Aureus (MSSA) – Another strain of *S. aureas*, MSSA has been under greater investigation of late as hospitals are seeing a rise in numbers as significant as that of MRSA. As the more treatable strain with antibiotics, it does not have the same

demand for testing as MRSA, but concerns as to mutation or inherent complications make this a key analyte in the panel.

- Vancomycin-resistant enterococcus (VRE) – Vancomycin-resistant enterococci (VRE) infection is the most common type of infection acquired by patients while hospitalized. Treatment of VRE is generally with other antibiotics other than vancomycin. During 2004, VRE caused about one of every three infections in hospital intensive-care units, according to the Centers for Disease Control and Prevention (CDC).

- Group A Streptococcal (GAS) – Two of the most severe, but least common, forms of invasive GAS disease are necrotizing fasciitis and streptococcal toxic shock syndrome. Necrotizing fasciitis ("the flesh-eating bacteria") is a rapidly progressive disease which destroys muscles, fat, and skin tissue. Streptococcal toxic shock syndrome (STSS) results in a rapid drop in blood pressure and organs (e.g., kidney, liver, lungs) to fail. About 9,000-11,500 cases of invasive GAS disease occur each year in the United States, resulting in 1,000-1,800 deaths annually

- Group B Streptococcal (GBS) - Group B strep (GBS) is a bacteria also known as *Streptococcus agalactiae*. This type of bacteria is commonly found in the human body, and it usually does not cause any symptoms, except in certain cases where it can be a dangerous cause of various infections that affect pregnant women and their newborn infants.

Market Summary

According to the U.S. Centers for Disease Control, every minute of every day, one person dies from sepsis in the U.S. (*CDC*). The most unfortunate aspect of this statistic is that often these deaths occur in the recovery treatment following standard surgical procedure. The first line of defense is hygienic programs among hospital staff, which includes regular hand-washing between patients and effective use of disinfectants. Hospitals are beginning to adopt surveillance testing programs in centers that do not show improvement in HAI rates with the hygienic programs. States including Illinois, Pennsylvania and New Jersey have initiated mandatory screening for MRSA in hospitals.

MRSA is driving the large growth in HAI testing due to a dramatic 30% increase in infections between 1995 to 2004 (*CDC*). The U.S. CDC estimates that MRSA now makes up more than 60% of hospital staph infections. The growing frequency of cases and increasing resistance to antibiotic treatment have driven states including Illinois, Pennsylvania and New Jersey to mandate screening for MRSA in hospitals.

Percentage of Staph Infections among U.S. Intensive Care Patients That Are Infected with MRSA

Year	Percentage
1995	38%
1996	40%
1997	45%
1998	50%
1999	59%
2000	60%
2004	62%

**Kalorama, 2009*

The available market for Illumina's molecular HAI panel is estimated at $100M in 2008, and growing at 17% annually (*Kalorama, 2009*). There are several commercially available kits for molecular HAI testing, but each of these are single-plex assays that range in price from $25 - $35 per test. Clinical labs are increasingly beginning to convert from traditional cultures to molecular tests due to the improved sensitivity, specificity, and rapid turnaround time. With difficult to culture pathogens such as MRSA and VRE, molecular testing is becoming readily accepted as the most effective test method. An important feature of these tests, however, is the ability to return a rapid result. Once infected, rapid identification is crucial to ensure appropriate and effective treatment. Traditional culture and plate methods normally take 24 to 48 hours, which is too long. The table below lists the most commonly used kits, and the sample volumes, reported by laboratory end users in the 2008 Emmes Molecular Testing Database. Note that the vast majority of the tests are performed by the hospital lab, further highlighting the need for rapid return of results.

Number of Molecular MRSA Tests by Vendor and End User (Hospitals by Bed Size, Reference Lab), 2008

Vendor	1 - 199	200 - 299	300 - 499	500 - 1000	>1000	Ref Lab	Total
BD/GeneOhm	151,630	89,300	195,800	257,750	7,500	42,450	744,430
Cepheid	99,050	111,900	212,500	206,800	5,600	36,900	672,750
Roche	10,000	9,450	35,000	0	0	7,000	61,450
Other	5,000	7,900	4,980	3,150	0	13,600	34,630
Total	265,680	218,550	448,280	467,700	13,100	99,950	1,513,260

**Emmes, 2008*

Competitive Advantage

In addition to providing a multiplex panel containing the major causative pathogens for Hospital Acquired Infections, enabling clinical laboratories to reduce costs, increase throughput, and reduce sample requirements, Illumina shall utilize the extremely rapid and robust EraGen modified base chemistry to provide the ideal workflow for an infectious disease lab. By incorporating their chemistry, Illumina will have one of the only multiplex panels that can go head to head with Cepheid in terms of turn around time and surpass them in throughput. Additionally, Illumina will be able to provide a significant cost savings to labs running these tests separately. When stacked, a laboratory running a similar panel using single-plex molecular assays could spend between $100 to $175 per sample, depending on volume. With a list price of $35 per sample, Illumina's HAI panel will drive adoption and enable affordable expansion of hospital surveillance programs.

Forecast Projections

	2010	2011	2012
# Samples	n/a	26,000	61,000
Revenue	n/a	$0.9M	$2.1M
ASP	$35	$35	$35
Est. GM%	75%%	75%	75%

iScanDx for Cytogenetics

Illumina's cytogenetics diagnostic product shall consist of a whole-genome Infinium BeadChip, scanner, and analysis/reporting software. The array and software will provide high-resolution genome-wide maps of copy number aberrations. The product will support multiple different cytogenetics applications, likely with a single array, but different analysis software settings. Prenatal and neonatal testing would be supported natively. Preimplantation genetic diagnosis (PGD) could be supported with an assay optimized for low DNA input and faster processing.

Market Summary

Worldwide, more than 1 million cytogenetic analyses are performed annually in more than 400 labs (Gersen and Keagle, 2005). The molecular cytogenetics market is large ($400-600M) and growing rapidly (15–20% CAGR). Microarrays are a relatively new technology to this market and currently account for about one third ($120M–200M) of the molecular cytogenetics market (the remainder consists of traditional techniques including FISH and MLPA). However, whole genome microarrays have the potential to supplant much of the use of traditional techniques. It is expected that microarrays will overtake FISH as the most common molecular cytogenetic technique by 2013 (Frost & Sullivan). Layering market share growth on the overall market growth presents a substantial opportunity, and the array-based cyto market could be more than $450M by 2012.

There are several compelling reasons for users of "traditional" molecular cytogenetic techniques to switch to arrays, all of which can only be maximized by providing a whole product offering that includes FDA approval.

1. There is the potential for much faster parallel analysis of the entire genome, rather than serial analysis with low-multiplex sets of FISH or MLPA probes based on suspected genomic aberrations related to phenotype.

2. Traditional cytogenetic analysis has a low diagnostic yield of 5-10% (Gijsbers, 2009). Early reports indicate that using microarrays as the front line test for DD/MR samples would raise the yield by at least an additional 20% (Slater, 2-29-09 BioArray News). Improved analysis workflows should raise this yield even higher.

3. The market is relatively pragmatic and relatively slow to adopt. Illumina's move to get approval for cytogenetic products will greatly substantiate our position as the leading platform and a "safe bet." Standardization should also support improved reimbursement for SNP array-based tests increasing the per-test revenue of our customers.

Competitive Advantage

Unlike our array competitors (e.g., Agilent, Nimblegen, and Affymetrix) our oligos are manufactured in large lots rather than synthesized individually on the array surface. This gives us a distinct advantage in a regulated environment where each lot must be tested and validated.

SNPs are very useful markers for cytogenetic analysis, and are broadly recognized as the next generation of cyto arrays in informal surveys conducted by Illumina at conferences. Illumina is uniquely able to target SNPs broadly. Affymetrix is limited in their ability to target SNPs, even though they market SNPs as being very important.

The ideal mainstream cytogenetics array is at a much lower multiplex level than that desired for many discovery research applications. At these sub-maximal multiplex levels, Illumina should be particularly competitive against Affymetrix in terms of cost of goods. Affymetrix doesn't have the multi-sample manufacturing economies of scale effects as we do since they likely need to use a full size mask, and thus are at a disadvantage to compete on price with Illumina in this market.

Forecast Projections

	2010	2011*	2012
# Samples	40,000	70,000	100,000
Revenue	$4.8M	$9.4M	$13.5M
ASP	$120	$135	$135
Est. GM%	80%	80%	80%

**Assumes 510(k) clearance end of Q1 2011*

Key Dependencies

- Securing IP rights to use Infinium Assay in diagnostic products
- Establish GMP manufacturing, including oligos, arrays, and reagents
- Improving system robustness
- Document remediation to bring the iScan instrument under design control, or creation of a new scanner under design control

Prenatal/Newborn Screening/IVF

Illumina predicts that in the not to distant future, children will be sequenced at birth as the ultimate form of newborn screening. Throughout their lives, their genome information will prove valuable from the early days of life where physicians can best care for a child with special needs, to the days when that child is ready to have children of their own and carrier status becomes an important component to parental planning, and into to late adulthood when multiple prescriptions can be better managed based on the individuals drug metabolism,

Not without controversy the concept of newborn sequencing is continually debated and is often a topic of discussion within the molecular diagnostic community. As a first step toward achieving this revolutionary goal Illumina's multiplexing technologies can be leveraged to combine the many genetic tests currently performed at birth to save cost, labor and valuable time toward identifying critical diagnoses' that can make a significant impact in the life of the child parentally and after birth.

Content may include but is not limited to the following:

- Aneuploidy screening for chromosomes 13, 15, 16, 18, 21, 22, X and Y.
- Gender identification and aneuploidy for X and Y.
- Common translocations
- Single gene disorders like cystic fibrosis, spinal muscular atrophy, sickle cell disease, huntingtons, henaglobinopathies, congenital adrenal hyperplasia, fragile X, connexin 26

- Ashkenazi Jewish Panel including bloom syndrome, canavan disease, familial dysautonomia, fenconi anemia, gaucher disease, Niemann-Pick, Tay-Sachs

Market Summary

The market for prenatal screening is approximately 4% of the total molecular diagnostics market at $150M in 2007 and is expected to reach $200M by 2012 with 6% CAGR. The total inherited disease market is also 4% of the total molecular diagnostics market at $135M in 2007 and is expected to reach $190M by 2012 with 7% CAGR. Of the total prenatal market approximately 50% or $75M can be attributed to FISH analysis, fluorescence in situ hybridization, for chromosomal abnormalities.

Companies are developing technologies to isolate fetal white blood cells from the mothers peripheral blood to perform parental tests without the invasive procedure of an amniocentesis. From those cells FISH and nucleic acid testing can be performed to identify genetic disorders. Companies developing these techniques include (*Kalorama 2006*):

- Monash University, Melbourne, Australia can isolate single cells from a fetus in the cervical mucus of a pregnant woman to use these cells to test for genetic abnormalities. Enzymes are used to free up the cells, fluorescent antibodies tag the fetal cells, which then can be analyzed by a variety of technologies.
- Invitrogen/Dynal, Oslo, Norway markets Dynabeads that have been used to isolate fetal white blood cells in maternal blood with immunomagnetic beads.
- Applied Imaging, Santa Clara, CA has received a U.S. patent for the detection of objects of interest - including rare cancer cells in tissue and blood, or fetal cells in circulating maternal blood - through the analysis of multiple microscopic images.
- Biocept, Inc., Carlsbad, CA, is developing a high-performance 3D HydroArray Chromosomal Disorders Diagnostic platform that can separate fetal cells from maternal blood.
- BTG, West Conshohocken, PA is developing FISH technology that has the ability to identify fetal DNA from the mixed cell population in the maternal bloodstream. Fetal cells are identified by the Telomere Depletion Assay based on the difference in telomere length between fetal and adult cells. Fetal chromosomes are known to have longer repeats of the telomeric DNA sequence.
- AVIVA Biosciences, San Diego, CA is developing a biochip to isolate fetal blood cells.
- Caltag Laboratories, Burlingame, CA markets a flow cytometry test, the Fetal Hemoglobin Test.
- Ravgen, Columbia, MD, is working on a method to isolate fetal DNA in maternal blood.
- Sequenom, San Diego, CA is developing Fetal Nucleic Acid Technology using maternal blood.
- Ikonisys, Inc., New Haven, is developing the image cytometry Chromotest to test fetal cells from the maternal blood for prenatal diagnosis of chromosomal abnormalities.

Many of the same techniques used for prenatal testing can be applied to preimplantation genetic diagnosis (PGD). PGD can be potentially used for prenatal genetic testing of cytogenetic and Mendelian disorders in embryos prior to being implanted in patients undergoing IVF.

U.S. and international newborn screening programs include many genetic diseases depending on the population served in that area. There are several working groups working, including the American College of Medical Genetics, to standardize Newborn screening across the United States to reduce variability in test menu and procedure. A comprehensive panel would contribute greatly toward that goal. (Watson et.al., *Genetics and Medicine*, May 2006.). Several developers of low plex molecular platforms offer individual tests covering much of the content needed for newborn screening but as of

today, no company has successfully commercialized a comprehensive panel that will change the methods of newborn screening reducing cost, labor and time to actionable result.

Competitive Advantage

Illumina's high multiplexing capability with excellent quality data provides a significant competitive advantage where other technologies can not reach a competitive multiplex level. Acquisition or development of a competitive non-invasive method of isolating fetal cells for genetic analysis will be critical to establish competitive advantage. Last, the technique used to perform the multipex assay must provide an answer quickly enough to allow appropriate intervention in all cases newborn screening, IVF and prenatal testing. Ideally such chemistries would provide results in one day although the market will likely tolerate a 2 day assay if the consolidated content and multiplex level justifies extra time.

Forecast Projections

	2010	2011	2012
# Samples	n/a	n/a	24K
Revenue	n/a	n/a	$2.3M
ASP	n/a	n/a	$95
Est. GM%	-	-	TBD

Key Dependencies

- Acquisition or development of technology for extracting fetal white blood cells from others periphery
- Content mix and reporting tools make sense for how the tests are ordered in practice
- Price of tests is significantly lower than running each independently to be considered disruptive
- The best platform for the panel is IVD cleared (BeadXpress or BeadArray technology)
- GM dependant on platform, content mix and content selected

Respiratory Viral Panel

Illumina's Respiratory Viral Panel shall be a multiplex molecular assay, detecting viruses and bacteria responsible for common respiratory illnesses. To compete against the Luminex RVP panel, and leverage it's 510(k) clearance, Illumina's panel shall be comprised of a 14-plex (plus 2 internal controls) assay targeting the viruses and bacteria listed below. The content contained with this panel will account for 85% of respiratory viral infections.

- Influenza A/B (Flu A/B) – Responsible for seasonal flu epidemics each year. Subtypes of Flu A can circulate more virulently (H1, H3).
- Human metapneumovirus (hMPV) - Compared with respiratory syncytial virus, infection with human metapneumovirus tends to occur in slightly older children and to produce disease that is less severe. Co-infection with both viruses can occur, and is generally associated with worse disease. It is estimated that hMPV is associated with 12% of lower respiratory illnesses that were characterized by wheezing, croup, or pneumonia. It also seems to be linked to 15% of common colds and about one third of complicated inner ear infections

- Human Parainfluenza 1/2/3 – Human parainfluenza viruses are second to RSV as a common cause of lower respiratory tract disease in young children. HPIV-1 is the leading cause of croup in children, whereas HPIV-2 is less frequently detected. Both HPIV-1 and -2 can cause other upper and lower respiratory tract illnesses. HPIV-3 is more often associated with bronchiolitis and pneumonia

- Respiratory syncytial virus (RSV) A/B – Respiratory syncytial virus (RSV) is the most common cause of bronchiolitis and pneumonia in children aged <1 year and is a major cause of respiratory illness in older adults. Each year in the United States, an estimated 75,000--125,000 children aged <1 year are hospitalized with RSV. Those at increased risk for hospitalization include premature infants and individuals with compromised respiratory, cardiac, and immune systems.

- Adenovirus B/C/E - Adenoviral infections usually affect infants and young children. Studies show that adenovirus accounts for up to 5% of acute respiratory infections in children and is often a cause of diarrhea. They are more prevalent in the winter, when children are often indoors with other children, as in school etc.

- Rhinovirus – The most common manifestation of rhinovirus, the common cold, is mild and self-limited. However, severe respiratory disease, including bronchiolitis, asthma exacerbations, and pneumonia, can occur, particularly in infants and young children.

Market

Each year, according to the U.S. Centers for Disease Control, an average of 5 – 20% of the population contracts the flu. Hospitalization results in some 200,000 patients, while about 36,000 die from complications of the flu (*CDC*). Most susceptible to complications are young children, senior adults, and those with immune deficiencies. Annual direct and indirect costs of flu viruses are estimated at $10 million, with the greatest impact in treating the young and immune compromised (*Kalorama, 2009*).

As with other infectious disease tests, the most currently used method is an immunoassay. However, the clinical market is increasingly turning to molecular methods in order to improve sensitivity, specificity, and turn-around time. The below table lists some of the considerations outlined in *Molecular Pathology in Clinical Practice*, (Leonard, 2007, p.462), a guidebook written and contributed by the leading molecular pathologists in the U.S.

Comparison of Nucleic Acid and Culture/Antigen Detection Methods for Respiratory Pathogen Detection

	Nucleic Acid Methods	Culture/Antigen Methods
Cost	Tests tend to be expensive (but getting cheaper)	Relatively inexpensive in labs already set up for these procedures, but "real" cost of maintaining cultures often underestimated
Speed	Rapid diagnostic methods	Speed very variable depending on the pathogen and method used
Infrastructure	Specialized laboratory set-up required	Specialized laboratory set-up required

Sensitivity	Exquisite sensitivity but can be prone to cross contamination problems	Generally less sensitive than nucleic acid methods
Specificity	Careful handling required to avoid contamination; primer/probe design crucial	Careful handling required to avoid contamination, but less-common problem than for molecular methods; DFA subject to over-interpretations
Strain typing	Most definitive method	Limited serotyping
Automation	Automated extraction equipment available; automated detection commonplace	Difficult to automate
Safety	Inactivated before analysis, but antimicrobial sensitivity information requires knowledge of genotype mutation	Isolates useful for antimicrobial sensitivity testing and phenotyping, but specialized safety requirements needed for culture of category 3 / 4 pathogens
Quality Assurance	Proficiency and validation of methods not well established but improving	Culture depends critically on cell line or medium quality; maintaining quality can be difficult

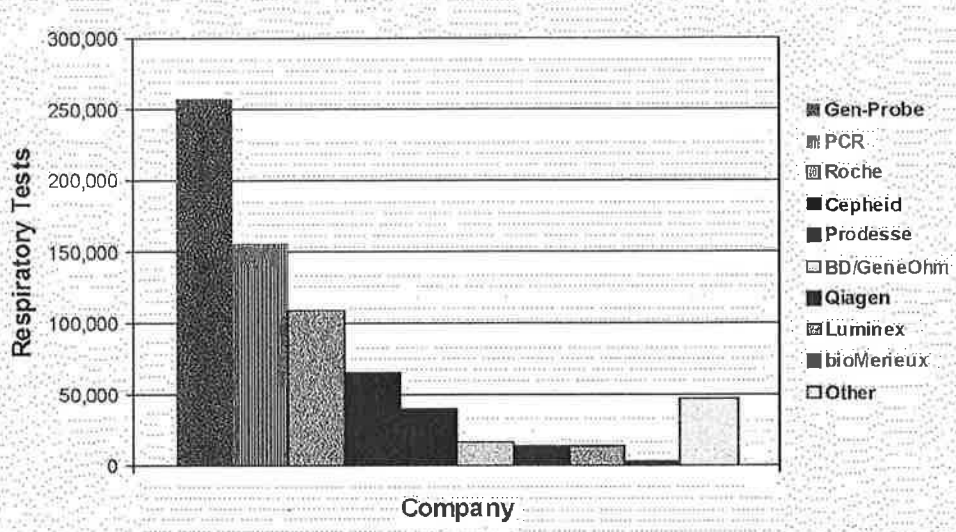
As highlighted in the table, several factors play into the adoption of respiratory pathogen testing. In the case of respiratory viruses, the timely return of results enables physicians to implement the proper targeted therapy based on specific molecular based tests, and not generalized guidelines.

Interim recommendations for the selection of antiviral treatment using laboratory test results and viral surveillance data, United States, 2008–09 season*

Rapid antigen or other laboratory test	Predominant virus(es) in community	Preferred medication(s)	Alternative (combination antiviral treatment)
Not done or negative, but clinical suspicion for influenza	Influenza A (H1N1) or unknown	Zanamivir	Oseltamivir plus Rimantadine†
Not done or negative, but clinical suspicion for influenza	Influenza A (H3N2) or influenza B	Oseltamivir or Zanamivir	None
Positive A	Influenza A (H1N1) or unknown	Zanamivir	Oseltamivir plus Rimantadine†
Positive A	Influenza A (H3N2) or influenza B	Oseltamivir or Zanamivir	None
Positive B	Any	Oseltamivir or Zanamivir	None
Positive A + B‡	Influenza A (H1N1) or unknown	Zanamivir	Oseltamivir plus Rimantadine†
Positive A + B‡	Influenza A (H3N2) or influenza B	Oseltamivir or Zanamivir	None

While the vast majority of molecular tests are still run under culture/antigen methods, there has been an increase in the number of multiplex test kits available on the market. These include the 510(k) cleared xTAG Respiratory Viral by Luminex, and EraGen's MultiCode-PLx Respiratory Viral Panel. These multiplex panels still have significant strides to make in order to achieve the market share currently held

by companies offering single-plex molecular tests. It is estimated that the available market is 1.2 million tests each flu season, and that the adoption of molecular methods is growing at a rate of 15% each year.



Competitive Advantage

Unlike the competitors listed above, Illumina shall enable clinical laboratories to reduce costs, increase throughput, reduce sample requirements, and minimize labor resources by commercializing a multiplex diagnostic panel, comprised of all three viral targets. In addition to the multiplexing capabilities, the VeraCode technology will enable inclusion of internal assay controls and controls to trigger automatic calling thresholds and data analysis reports. Finally, this plan assumes that the assay shall benefit from the EraGen chemistry, enabling results within three hours and requiring less than 30 minutes of hands-on time.

Forecast Projections

It is important to note that unlike other panels, the Respiratory Viral Panel will be a seasonal product. In the United States, the flu season typically runs from November to April.

	2010	2011	2012
# Samples	n/a	n/a	25,000
Revenue	n/a	n/a	$1.25M
ASP	$50	$50	$50
Est. GM%			80%

Key Dependencies

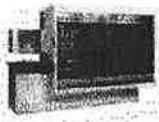
- Complete EraGen / ILMN agreement; enable development with EraCode modified bases
- R&D developers experienced in designing assays with viral targets
- Access to viral & bacterial targets for assay development
- Performance meets or exceeds performance demonstrated by Luminex RVP as predicate device for FDA submission
- Ensure that product is available before the start of the flu season in order to recognize revenue in the year of release

BeadXpress II

To maximize the opportunity with of products within the Dx development portfolio, a fully automated system, able to manage sample extraction to data reporting, is necessary. Tests that require high throughput capabilities and minimal hands-on time, such as newborn screening and HAI, will experience greater adoption into the clinical market. Particularly with some of the higher multiplex panels utilizing FastGG, an automated system would eliminate the challenge of tedious pipetting and wash steps since it would not require technician time. The system will be developed under design control and submitted for clearance by the FDA.

Market Summary

Amid a nationwide shortage of clinical laboratory technicians, daily testing requirements for clinical labs continue to grow. It is estimated that US laboratories will need approximately 12,400 professionals annually between 2002 and 2010. The average number of clinical laboratory personnel expected to enter the job market is approximately 4,200 people per year (wafeeew). Additionally, with insurance payors looking to pay less and less per test, both science and economics are driving the influx of automation for molecular tests. To address this, several commercial companies have released automated systems for clinical use. These are formatted to provide a "sample in, answer out" ease of use. The clinical market is not funded for capital equipment purchases, so the instrument systems are a function of reagent rental contracts, rolled into the overall price per test (or placed at no charge in some instances).

	Competitors	Features
	**Roche COBAS**	Combine AmpliPrep andTaqMan® Analyzer,the system performs automated sample prep, amp, and quantitation of RNA or DNA.
	**Cepheid GeneXpert Infinity**	Fully automated: sample in, answer out. Manages the sample data, cartridge loading and unloading and reporting of test results. RUO and diagnostics. Up to 2,074 tests during per 24 hours.
	**BioRad BioPlex 2200**	1st diagnostics multiplexing platform on a fully-automated platform. Process 100 samples/hour, yielding <=2200 results, with 8 hours of walk-away capability. Autoimmune diagnostics.
	**AutoGenomics INFINITI**	Sample handling, reagent management, hybridization, stringency and detection for DNA analyses. "Load N Go" concept. FDA clearance on two assays using INFINITY.
	**Inverness Medical AIMS**	The 1st space-efficient, integrated, fully automated, open, multi-methodology system. Work with AtheNA Multi-Lyte® reader and ELISA reader.

Competitive Advantage

Based on feedback from reference laboratories and clinical customers, Illumina's BXII would be designed to accommodate the desire for complete sample to answer functionality, and support Illumina's diagnostic product pipeline.

LIST PRICE OF SYSTEM	$150,000 – $250,000
TARGET CUSTOMERS	CLIA High Complexity Lab, centralized clinical testing lab, clinical research labs, molecular diagnostic test developers, hospitals, and pharmacogenetics labs
OPERATIONAL SOFTWARE USER INTERFACE	Touch-screen operation; multi-menu selection Barcode scanning of samples/reagents (LIMS) Automated "calling" per test type; different user rights; Integration with other patient management software Support FGG and current VeraCode assay workflows
THROUGHPUT	Flexible range from 8 samples to 96-samples at once In-series run of up to ten 96-well plates Sample to answer time: ~ 6.5 hours, or less than 3 for ID
REAGENTS & CONSUMABLES	Pre-kitted reagent "cassettes" or "packs" Disposable tips/plates (off-the-shelf)
AUTOMATION	Walk-away operation, sample to answer
SAMPLE PREP	Optional Nucleic acid & protein extraction from: whole blood, saliva, buccal swabs, CSF, serum, blood cards
REGULATORY	Regulatory Design Control – GMP Manufacturing with FDA/CE-IVD clearance intention
MANDATORY MODULES	Nucleic acid isolation, Pre-PCR, Post-PCR, Hybridization and wash, Read and data analysis

Forecast Projections

	2010	2011	2012
# Systems	n/a	n/a	45
Revenue	n/a	n/a	$8.6M
ASP	n/a	n/a	$190,000
Est. GM%			49%

Diagnostic Targeted Sequencing (Prometheus II)

Held by the clinical molecular diagnostics industry as the "gold standard", sequencing technology has been used Leveraging the advances of the RUO Avantome sequencing system (aka., Prometheus), the next generation of the Avantome technology will be developed to meet the requirements of the diagnostics market. Significant opportunity exists within diagnostics for targeted sequencing of virus, bacteria, and genes associated with complex diseases.

Competitive Advantage

Illumina's Dx sequencing system will enable high throughput sequencing unsurpassed in the industry and a price that is affordable for entry into clinical diagnostic use. With the ability to perform targeted sequence analysis with accuracy and precision greater than 99.9%, the throughput capabilities will

enable clinical labs to replace their current routine testing technology with sequencing in areas such as Cystic Fibrosis, infectious disease/viral typing, HLA typing, Blood Group Typing, etc. To date, the expense, time to result, and low throughput capabilities of CE sequencing have limited its use clinically except in the instances of confirmatory testing. It is estimated that the market opportunity is $300M and will grow at a rate of 20% per year once available.

Forecast Projections

Based on the development times for a major system developed under regulatory design control, we do not anticipate commercialization until 2013. However, development will need to be initiated and resourced by Q2 2011.

Key Dependencies

- Project resourced and scoped to require regulatory Design Control
- Simplified sample prep and assay prep – automated preferable
- Price point around $200 - $230k
- Open platform capabilities to enable early adopters prior to 510(k) cleared tests

CLIA Lab Diagnostic Services

The technologies and expertise within Illumina's CLIA service lab make it uniquely suited to target emerging applications within the relatively conservative clinical space. Fueling the interest in Illumina's CLIA lab is the potential to utilize next gen sequencing technology to resolve unmet needs in areas such as organ transplantation, HIV drug resistance, and cancer. Illumina's development pipeline for the CLIA lab services shall include:

- HLA Typing
- HIV Drug Resistance Testing
- Cancer Panel

For each of these programs, Illumina's sequencing technology provides significant competitive advantage over Sanger Sequencing, which is the current standard for diagnostic sequencing. Because the GA is unable to compete with the turnaround time, Illumina will focus on applications where there is a longer lead time allowed due to the need for as comprehensive an analysis as possible.

Comparison of Sequencing Specifications – ILMN vs. Sanger

	ILMN GA	Sanger
Coverage used to report	Ave. 30x, minimum 5x for all bp reported	2x
Bi-directional	Yes	Yes
Read lengths	75 bp x2 = 150 bp	<500 bp
Intron coverage	Yes	unusual
Detect insertions, rearrangements	Yes	usually
Max throughput/run	15,000,000,000 bp	15,200 bp

Throughput/day	>166,000,000 bp/day	328,000 bp/day
Runs/day	1 run = 4 – 9 days	41 runs/24 hours
Time for sample prep (including DNA extraction)	3 – 4 days	2 – 3 days
Accuracy in sequence reporting	>99%	98.5% - 99%

As an emerging field, very little market information is available at this time. However, discussions and interviews with customers and potential business partners have provided insight to desired content and approach.

Key Dependencies

- Simplified/Automated sample prep
- Targeted sequencing
- Bioinformatics
- Clinical Reporting
- Biosafety Level II (+)
- Additional CLIA License
- Dx Services sales team
- Direct to physician/pathologist marketing

Human Leukocyte Antigen (HLA) Typing

Illumina's HLA Typing service shall be developed for organ transplantation compatibility testing, and focused on solid organ and bone marrow transplantations. Within this field, state-of-the-art analysis is embraced in order to limit the likelihood of transplant rejection. Illumina shall provide deep sequencing service for examining the MHC on chromosome 6. These genes are very polymorphic between individuals and they code for antigen production. There are two main classes of HLA genes – Class I which includes HLA-A, HLA-B and HLA-C; and Class II which includes HLA-DR, HLA-DP and HLA-DQ. Because these genes are so variable, DNA sequencing is the gold standard for genetic analysis of HLA.

Table of variant alleles

Number of variant alleles at Class I and Class II loci according to IMGT-HLA database, last updated January 2009

MHC Class I		MHC Class II				
Locus	#	HLA	-A1	-B1	-B3 to -B5[1]	Potential
Major Antigens		locus	#[5]	#[5]	#[5]	Combinations
HLA A	767	DM-	4	7		28
HLA B	1,178	DO-	12	9		72
HLA C	439	DP-	27	133		3,591

Minor Antigens		DQ-	34	96		3,264
HLA E	9	DR-	3	618	82	2,121
HLA F	21					
HLA G	43					

The U.S. accounts for 60% of organ transplants world wide. It is a mature market, and between 2005 – 2008a, there were an average of 28,344 organ transplants and 20,000 bone marrow transplants each year. With each transplant, there are typically 3 tests performed, one on the recipient and one for each of two high potential donor candidates. At an average price of $1,200, this brings the combined market to approximately $127M. Within the CLIA registry, there are a total of 186 CLIA labs certified to perform transplant testing. Below are examples of competitor labs and their test price for high resolution HLA typing.

NMDP Transplant Center Name	High
University of Pittsburgh Medical Center	$603
City of Hope National Medical Center	$1,755
Thomas Jefferson University Hospital, Inc.	$1,335
University of Mississippi Medical Center	$1,335
Cedars-Sinai Medical Center	$1,335
Mount Sinai Hospital	$1,335
University of Kansas Medical Center	$1,470
Western Pennsylvania Cancer Institute	$1,346
Tulane University Hospital and Clinic	$1,635
Christiana Care Health Services	$2,562
Roger Williams Medical Center	$1,400
University of Kentucky Medical Center	$1,250
Medical University of South Carolina	$1,335
University Medical Center	$3,560
LDS Hospital	$2,200
St. Francis Hospital and Health Centers	$1,750
St. Louis University Hospital	$2,509
NMDP Transplant Center: City of Hope Banner	$1,175
Emory University Hospital	$1,000
Presbyterian/St. Lukes Medical Center	$1,500
Beth Israel Deaconess Medical Center	$2,280
M.D. Anderson Cancer Center	$1,207
Hackensack University Medical Center	$1,468
New York Presbyterian Hospital at Cornell	$2,500

**OPTN*

Forecast Projections

	2010	2011	2012
# Samples	260	570	720
Revenue	$0.78M	$1.7M	$2.1M
ASP	$3,000	$2,900	$2,900
Est. GM%	60%	60%	60%

HIV Drug Resistance Testing

While most of the third world struggles with the basics of HIV diagnosis, HIV has become akin to chronic disease in the U.S. and is managed through proper adjustment of drug treatment options. Growth in the market is derived primarily from HIV genotyping assays to determine a patient's sensitivity to these drugs. It is estimated that the U.S. market for HIV genotyping tests (primarily by sequencing technology) was $145 million in 2008 (*Kalorama*). With the very limited Sanger sequencing used currently, the cost per test is approximately $250. Illumina's sequencing assay will be better adapted for high throughput volumes (indexing) and will generate unsurpassed accuracy and precision, enabling better selection of drug treatment.

Forecast Projections

	2010	2011	2012
# Samples	100	300	760
Revenue	$42,500	$127,500	$323,000
ASP	$425	$425	$425
Est. GM%	60%	60%	60%

Of key concern to enabling the forecast is the turn-around time for sequencing using the GA. It cannot take weeks to return results.

Cancer Panel

As shown in the section detailing Illumina's oncology program (pg. 6), the market for diagnostic testing of cancer is a large and rapidly growing segment that Illumina can enter. Molecular methods in oncology have become popular due to their sensitivity, and there are none that surpass sequencing. Illumina's service shall consist of a cancer panel for somatic mutations profiling and shall include:

- KRAS - KRAS mutations are found in 35% to 45% of patients with colorectal cancer. A KRAS mutation test helps physicians know whether these patients are likely to benefit from therapies such as Erbitux® and Vectibix®. Studies have shown that the normal form of the KRAS gene is associated with response to these therapies, while patients with a mutated KRAS gene are less likely to respond. Recently the American Society of Clinical Oncology (ASCO) and the National Comprehensive Cancer Network (NCCN) have recommended that patients with metastatic colorectal cancer should receive KRAS mutation testing.

- P53 - Mutations in p53 are present in greater than 50 percent of all human cancers, including colon, breast, lung, bladder, brain, liver, and hematological malignancies. Germline (heritable)

mutations in the p53 gene predispose individuals to various tumors associated with Li-Fraumeni syndrome. Identification of p53 gene mutations in cancer patients from Li-Fraumeni syndrome or Li-Fraumeni syndrome-like families may permit identification of individuals at high risk for cancer in these families.

- Additional genes that would be targeted are:

ABL1	CDK	FGFR3	MET	PIK3CA
AKT1	EGFR	FLT3	HRAS	RET
AKT2	ERBB2	JAK2	NRAS	
BRAF	FGFR1	KIT	PDGFR	

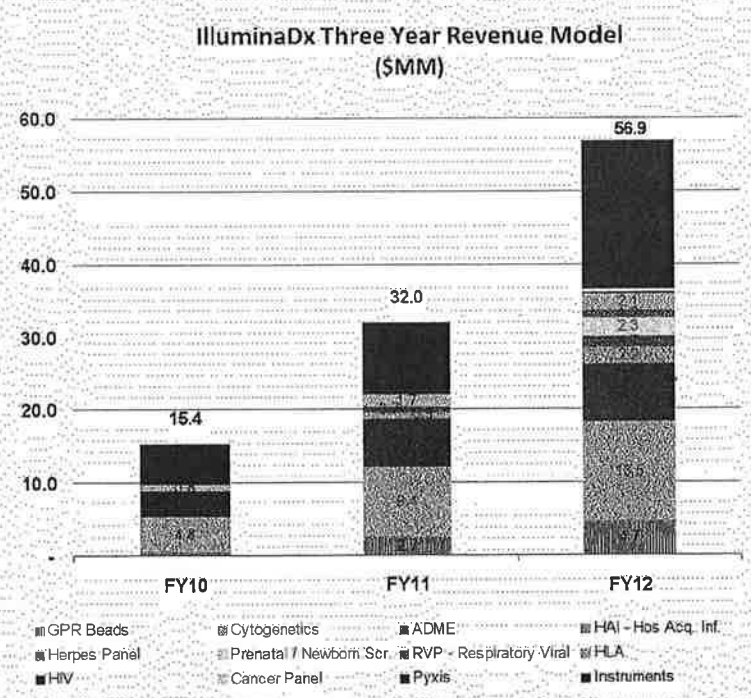
Forecast Projections

	2010	2011	2012
# Samples	n/a	n/a	110
Revenue	n/a	n/a	$187,000
ASP	n/a	n/a	$1,700
Est. GM%			60%

Financials

Three Year Revenue Summary

If executed to the timelines shown in the platform portfolio plan, Illumina will have significant growth over the next four years, with $57 million contributing from diagnostic products and services. Note that



the products commercialized in FY10-FY12 establish the install based of BeadXpress instrument systems, which will facilitate rapid commercialization of Illumina's proprietary cancer test when it becomes available as anticipated in 2013. With the necessary resources and development support, Illumina should anticipate doubling our growth for the next several years in the diagnostics business unit.

Development Costs

{Still in Process – Mike to provide soon}

Internal Dependencies

Many dependencies gate Illumina's development efforts and entry into the diagnostics market. It is critical that the items outlined in the table are supported by key department executives and managers.

Short Term Needs = 1 year ; Mid Term Needs = 3 years; Long Term Needs = 5 years

	Short Term Needs	Mid Term Needs	Long Term Needs
Instrumentation	• Improved robustness of BX system • FDA clearance of BX system • Improve robustness of iScan systems; establish standard system check/calibration method • Develop Avantome II under Design Control; enable "open platform" capabilities at initial launch	• Simplification and cost reduction of instrument systems (QSR manufacturing in Singapore or contract manufacturer) • Regulatory path for iScan (either DMR or 510k clearance) • Regulatory path for Avantome (either DMR or 510k) • Pull-out and indexing for Avantome (extremely robust performance needed)	• Different technology for rapid multiplex infectious disease testing
Automation	• Automation for liquid handling steps of Laguna assay	• Fully automated system, from extracted DNA to	• Fully automated system, from sample extraction through to

	• Automation that allows user to integrate into their LIMS system	assay workflow, then plate loading into instrument system	data analysis. Capabilities of running high throughput, 24/7 operation.
Assay / Technology	• Robust, scalable, multiplex assay • Custom assay design capabilities (similar to custom GGGT, but faster assay, lower plex and low cost) • Less expensive, less complex workflow • Single shift assay, for multiplex testing for genetic disease	• Low-plex assay with less than 1hr hands-on time and overall TAT of 4 hours or less • Simplified assay workflow for targeted re-sequencing – geared toward clinical labs • Circulating cell capture technology • Cytogenetics kit – cleared by FDA for use as IVD	• Ownership of proprietary markers for Dx application that is driven by important market need • Sample extraction kits/reagents compatible with automation solution • Diagnostic test menu for sequencing (targeted reagent kits) – cleared by FDA
Manufacturing	• 2-5x lot size • Scalable VeraGator • 2nd H2 Loader • Increase Tput per laser (taller phase masks, increase laser power) • 2nd Filament supplier • Metrology for kitted plates • Improvements in bead-removal • QSR compliant manufacturing for BX and VeraCode Dx reagents • Reduced COGS of VeraCode beads • GMP oligo manufacturing & post-processing • Space for equipment / expansion of manufacturing	• 20-30x lot sizes • 2nd MFG site • Efficiency – automated kitting • Custom multiplex bead plate flexibility on small and large scale • Larger lot sizes for bead pools (BeadArray) • Larger lot sizes for Avantome CMOS chips • QSR compliant manufacturing for iScan and select BeadArray, and Avantome products for Dx	• Continued COGs reduction • Manufacturing automation improvements
Software/Analysis	• System and analysis software submitted	• Ability to design/add select Dx partner	• Full tracking/incorporation

	for clearance with BX 510(k) submission. Framework for additional Dx test modules • Ability to be incorporated with LIMS of clinical lab • Automated design of custom FastGG assays (mini-OPAs); critical for Dx partnerships; needs incorporation into manufacturing (LIMS) • Revised KaryoStudio to optimize for clinical use • Bio-informatics analysis support for oncology biomarker discovery program • Filtered reporting for all instrument platforms used for diagnostics	modules to VeraScan • Unique normalization for test specific data analysis modules • Full tracking/incorporation with LIMs as part of automation. • Clinical reporting requirements with CPT coding – for FDA cleared tests and Illumina's CLIA lab	with LIMs as part of automation – from sample to analysis
Regulatory / Quality / Legal	• Guidance / strategy to efficiently gain FDA approval of BX • In-house Regulatory expert • Formalized complaint handling and CAPA program (tying SFDC to complaint resolution) • Regulatory pathway for iScan systems into clinical use • T's & C's for GPR beads to support Dx partners; diagnostic use of BX (when	• Formalized Clinical / Regulatory Group • Re-structured Dx advisory board – oncologists, etc. • Chain of control process (receiving of bio-materials/samples)	• Application/Indication specific Diagnostic Advisory Board sub-groups • PMA(?) for cancer panel

	cleared) • Chief Medical Officer (for safety board and re-imbursement program) • Intensive regulatory training for key area managers		
Field Service & Support	• Active Preventative Maintenance program for instruments • Specialized FAS individuals dedicated to clinical accounts • Specialized TechSupport individuals dedicated to specific clinical account management	• 24/7 response for clinical customers • Designated "Dx" field support team for clinical customers (FAS, FSE and Tech Support) • Rapid field repair/replacements and/or loaner program	• CEU credits for ILMN training classes
Sales Channel	• Sales specialists that target 1st tier clinical accounts (large reference laboratories) • Diagnostic partners, utilizing BX and GPR beads for product development and commercialization • Sample evaluation programs • Reagent rental / Leasing programs • Loaner pool for instrument evaluations	• Separate Diagnostic Sales team, focused on sales of Illumina's diagnostic portfolio exclusively • Evaluate distributors for ILMN diagnostic products • International diagnostic distributors	• Diagnostic Sales team, with "key account managers" who manage sales to diagnostic partners
Marketing	• Development of Illumina Diagnostic branding and identity • Target general human genetics and MDx conferences • Focus sessions on	• Targeted marketing campaigns for application areas (blood typing, infectious disease etc.) • Product management by	• Expansion of Dx marketing team; activities exclusive to Dx products only.

	"Laboratory Developed Test Applications" • Develop co-marketing programs with Dx partners	disease area / application • Dx partner / ILMN user group meetings (annually)	
Other	• Reimbursement specialist	• Health economics – CPT code establishment for cancer panel etc., works with lobbying group and AMA	• Lobby firm in DC • CPT code submission specialist (AMA)
CLIA Services	• Menu of CLIA testing services • Validation of platforms • Additional certifications – histology; virology • Genetic counselor or counseling service	• CLIA lab space expansion • Headcount expansion for CLIA lab technicians • Additional instrumentation for lab (Avantome, MagSweeper, iScan, Bruno) • Dedicated sales team • Outward bound direct marketing	• On-site physician/Chief Medical Officer • Automated production scale testing

Risks

Key risks to the program and achieving the revenue forecast are:

- Failure to address dependencies listed in above table
- Delays in BX 510(k)
- Failure to design "must-have" content into ADME core
- Failure to discover clinically relevant biomarkers
- Inability to provide sufficient resources to support commercialization activities and sales
- Delays in QSR compliance
- Skepticism by customer on ability for ILMN CLIA lab to support true clinical testing
- Direct competition in clinical services by major reference labs such as LabCorp and Quest
- Lack of resources to meet manufacturing and production needs

References

Market Analysis Data

- *Who's Doing What in Molelcular Dx*, The Results of the Kalorama Information/Emmes Group Survey of U.S. Laboratories, April 2009, Kalorama Information
- *The Worldwide Market In Vitro Diagnostic Tests*, 6th Edition, May 2008, Kalorama Information
- *Centers for Disease Control*, www.cdc.gov
- *The Emmes 2008 Molecular Testing Database*, The Emmes Group Inc., Boston
- *GeneTest at NCBI*, www.ncbi.nlm.nih.gov/sites/GeneTests/*s.org*
- *Organ Procurement and Transplant Network*, http://optn.transplant.hrsa.gov/latestData/viewDataReports.asp

Exhibit 315

1-315

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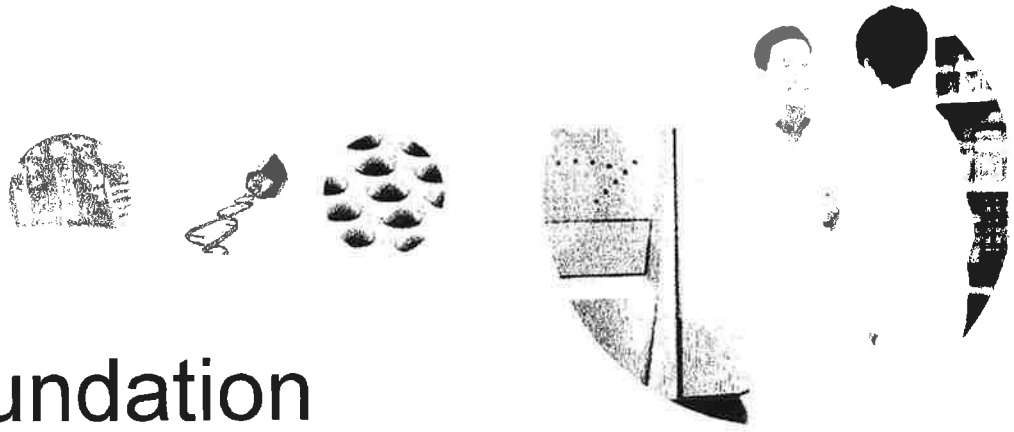

Gates Foundation Pathogen Detection Grant

Presented By:
Tim McDaniel
7/26/07

Background

Illumina is a recipient of a **subcontract** as part of a Gates Foundation grant to the University of Maryland

Purpose of grant is to assess emerging molecular diagnostics techniques as tools for epidemiological surveillance of microbial disease

- Illumina GoldenGate
- Sequencing (454!)
- IBIS TIGER assay (Multiplexed PCR followed by ionization electrospray Mass Spectrometry)

Illumina will make a modified GoldenGate assay targeting signature sequences from 33 diarrheal pathogens

The competing technologies will be tested head-to-head on the same panel of 3,000 typed field specimens collected from children's clinics in the developing world

Significance & History

Diarrhea is the largest killer of children <5 y o worldwide, accounting for 10 - 20% of all deaths in this age group

>30 different pathogens can cause pediatric diarrhea

Gates Foundation would like to fund vaccine development, but no comprehensive studies have been done to enable ranking the pathogens in importance, so priorities can't be established

Gates has provided a ~$30M grant to the University of Maryland's Center for Vaccine Development to comprehensively survey the causes of pediatric diarrhea in 6 field clinics in some of the world's poorest places

- Bamako, Mali
- MRC, The Gambia
- CDC site, Western Kenya
- Manhica, Mozambique
- NICED Kolkata, India
- ICDDRB, Dhaka (Mirzapur) Bangledesh

At each site fecal samples will be collected from >2500 cases and matched controls over three years

Samples will be typed by current gold standard microbiological tests to determine present agents

Prevalence of agents in cases versus controls will be used to establish major causes of disease

Significance & History (Continued)

Gates Foundation realized the sample collections generated by the main study would be ideal test set to assess emerging technologies & solicited Maryland to submit a proposal

Grant was awarded in June 2007 and funding started in September '07

Three sites from main study will provide DNA & cDNA samples from stools collected from 2,000 cases and 1,000 controls

Field sites will collect DNA and cDNA from stools, send to Maryland, who will then distribute to three technology test sites, including ILMN

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Details of Grant

Title: ***New Technologies in Diagnosis of Enteric Disease***

PI: James Nataro, MD, Ph.D.

Project Duration: 3 years

Start Date: Sept. 1

Funding: $5,567,836

Illumina's portion: $831,562*

33 bacteria, viruses and protozoa included in study

***This amount represents approximately three hours of interest from the Foundation's $34B endowment**

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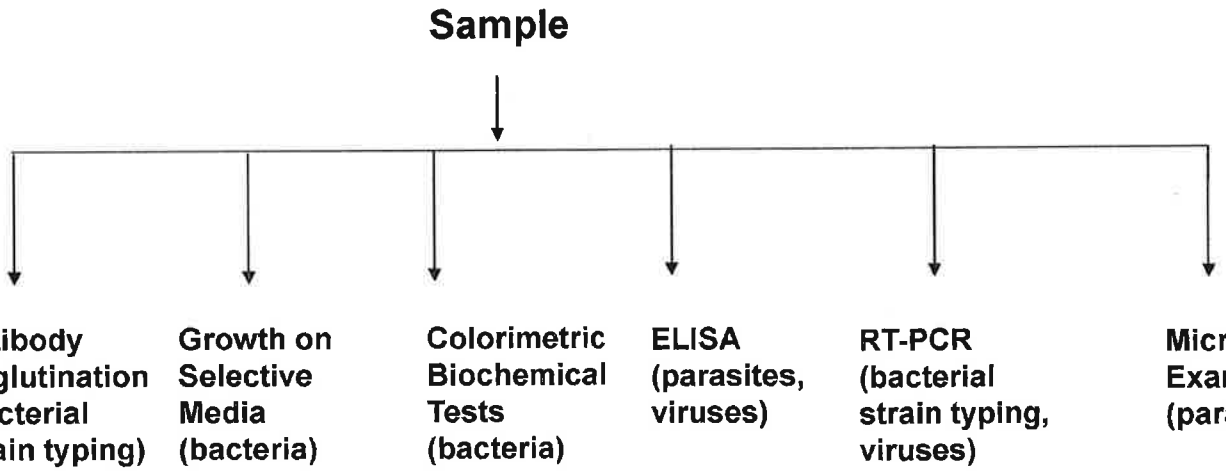
Current Diagnostic Methodology



- Many types of equipment
- Many different consumables
- Many skills required

- For main Study, current cost of diagnosis is $72/sample, even though most of the labor is being conducted in the developing world

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GoldenGate Diagnostics

Sample

GoldenGate

Diagnosis
(bacteria, viruses, parasites)

- **One setup**
- **One method**
- **One interpretation**

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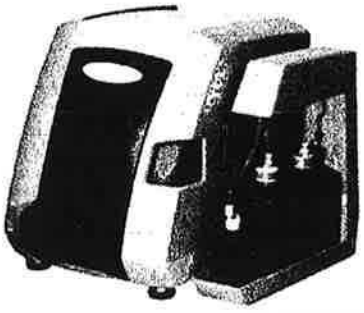
Project Phases

Period	Goal
Year 1 First six months	Develop screening array for 33 pathogens **on Sentrix Array Matrix**
Year 1 Second 6 months	Reduce assay time to <9.5 hours for 16 samples Design simplified software Select best primer sets by screening against defined samples
Year 2	Remake primer set on **VeraCode platform** using 10 best probes per organism Test against 1500 field specimens
Year 3	Select 5 best probes per organism based on Year 1 results Test against 3,000 field specimens



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Year 1 Milestones

Milestone		
Reduce GoldenGate Assay Time from three days to one		
Design and Manufacture test array		
Test Probes against spiked samples to identify best probes per organism		
Design turnkey software for assay run & analysis		

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Year 1 Milestones

Milestone	Status	Comments
Reduce GoldenGate Assay Time from three days to one	All-but-complete—Assay times reduced to enable single-shift assay	Currently at 22 hours due to use of 16-hour hybridizations on SAM
Design and Manufacture test array	1st pass complete for bacterial pathogens	Need guidance for input sequences for design of viral and protozoan probes
Test Probes against spiked samples to identify best probes per organism	1st pass Complete for bacterial pathogens	Need to repeat with expanded target repertoire for several pathogens
Design turnkey software for assay run & analysis	Delayed	Awaiting design of final probes. Does not gate any other part of program

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Main Experiments, Year 1

Experiment	Type	Probe set Multiplex	Biotinylation	Purpose
1	Probe set screening	362	Chemical	Select 96 best probes from a large number of candidates
2	Probe set screening	96	Primer Extension	Test best probes under "fast gg" biotinylation conditions. Further select probes
3	Dose-response	24	Chemical	Establish LOD of probes in Experiment 2
4	Dose-response	22	Primer Extension	Establish LOD of probes in Experiment 2
5	Unknown Panel	22	Primer Extension	Panel of unknows

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Experiment 1: Standard GG detection & specificity

Legend

Sample #	Organism
1	EPEC 2348/69
2	Shigella-flexneri
3	ETEC H10407
4	Aeromonas-gyrinophilus
5	Shigella-boydii
6	Vibrio-parahaemolyticus
7	Salmonella-typhii
8	Campylobacter-jejuni
9	Salmonella-typhi-murium
10	EAEC 042
11	Vibrio-cholerae 0139
12	Salmonella-enteritidis
13	Vibrio-cholerae 01
14	EHEC 0157:H7
15	Shigella-sonnei
16	Shigella-dys-1

Plate Layout

	1	2	3	4	5	6	7	8	9	10	11	12
A	1	1	1	1	1	1	9	9	9	9	9	9
B	2	2	2	2	2	2	10	10	10	10	10	10
C	3	3	3	3	3	3	11	11	11	11	11	11
D	4	4	4	4	4	4	12	12	12	12	12	12
E	5	5	5	5	5	5	13	13	13	13	13	13
F	6	6	6	6	6	6	14	14	14	14	14	14
G	7	7	7	7	7	7	15	15	15	15	15	15
H	8	8	8	8	8	8	16	16	16	16	16	16

+ BKGD
- BKGD

10,000 copies of each organism (based on molecular weight) were tested, with or without 100 ng human gDNA.

362 probes (all the probes initially designed) were included.

There was no significant difference in signals between samples with or without human background gDNA.

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Experiment 2: Fast GG detection & specificity

Legend

Sample #	Organism
1	EPEC 2348/69
2	Shigella-flexneri
3	ETEC H10407
4	Aeromonas-gyrinophilus
5	Shigella-boydii
6	Vibrio-parahaemolyticus
7	Salmonella-typhii
8	Campylobacter-jejuni
9	Salmonella-typhi-murium
10	EAEC 042
11	Vibrio-cholerae 0139
12	Salmonella-enteritidis
13	Vibrio-cholerae 01
14	EHEC 0157:H7
15	Shigella-sonnei
16	Shigella-dys-1

Plate Layout

	1	2	3	4	5	6	7	8	9	10	11	12
A	1	1	1	1	1	9	9	9	9	9	Human BKGD Only	Human BKGD Only
B	2	2	2	2	2	10	10	10	10	10	Human BKGD Only	Human BKGD Only
C	3	3	3	3	3	11	11	11	11	11	Stool Sample #1	Stool Sample #1
D	4	4	4	4	4	12	12	12	12	12	Stool Sample #1	Stool Sample #1
E	5	5	5	5	5	13	13	13	13	13	Stool Sample #4	Stool Sample #4
F	6	6	6	6	6	14	14	14	14	14	Stool Sample #4	Stool Sample #4
G	7	7	7	7	7	15	15	15	15	15	Stool Sample #5	Stool Sample #5
H	8	8	8	8	8	16	16	16	16	16	Stool Sample #5	Stool Sample #5

+ BKGD
- BKGD

10,000 copies/organism were tested at 96-plex.

Again, no differences were noted between + and – human background gDNA.

24 best probes were chosen for Experiment 3.

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Experiment 3: Dose-Response Test (Standard GoldenGate)

	EPEC	*Shigella-flexneri*	*ETEC*	*Aeromonas-gyrinophilus*	*Vibrio-parahaemolyticus*	*Salmonella-typhi*	*Campylobacter-jejuni*	*EAEC*	*Vibrio-cholerae 01*	*EHEC*	*E. coli Mix*	BKGD
	1	2	3	4	5	6	7	8	9	10	11	12
A	500000	500000	500000	500000	500000	500000	500000	500000	500000	500000	5000 (each) + BKGD	BKGD Only
B	100000	100000	100000	100000	100000	100000	100000	100000	100000	100000	5000 (each) + BKGD	BKGD Only
C	10000	10000	10000	10000	10000	10000	10000	10000	10000	10000	5000 (each) + BKGD	BKGD Only
D	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	5000 (each) + BKGD	BKGD Only
E	500	500	500	500	500	500	500	500	500	500	5000 (each) - BKGD	BKGD Only
F	100	100	100	100	100	100	100	100	100	100	5000 (each) - BKGD	BKGD Only
G	10	10	10	10	10	10	10	10	10	10	5000 (each) - BKGD	BKGD Only
H	1	1	1	1	1	1	1	1	1	1	5000 (each) - BKGD	BKGD Only

The number of copies tested ranged from 1 to 500,000.

LOD samples were tested without human gDNA background.

Of the 10 organisms tested, 8 showed good dose-response curves, but 2 (ETEC and EHEC) showed poor detection and were excluded from the following experiment.

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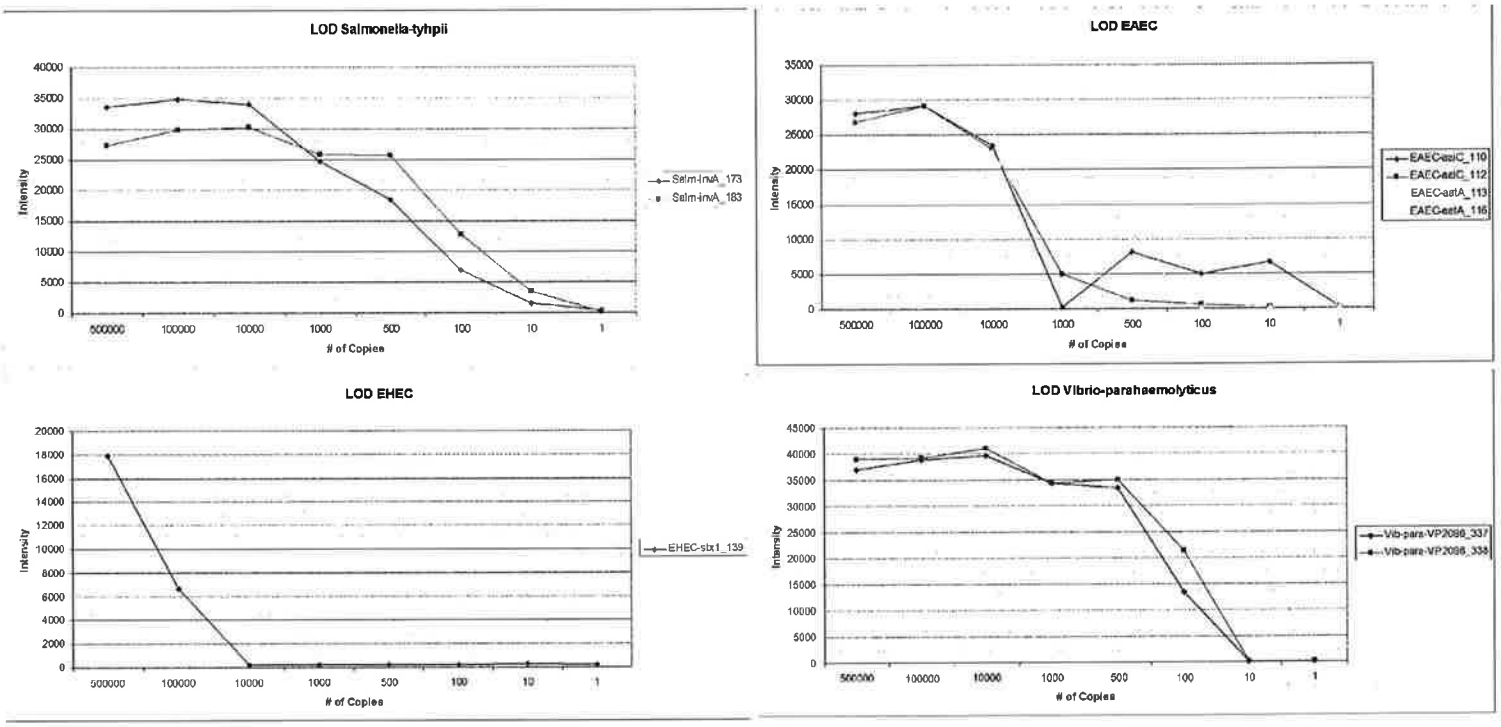
Dose-response Graphs From Experiment 3



For 8 organisms, LOD appears to be 10-500 copies.

For EHEC and ETEC detection is not reached until10,000 copies.

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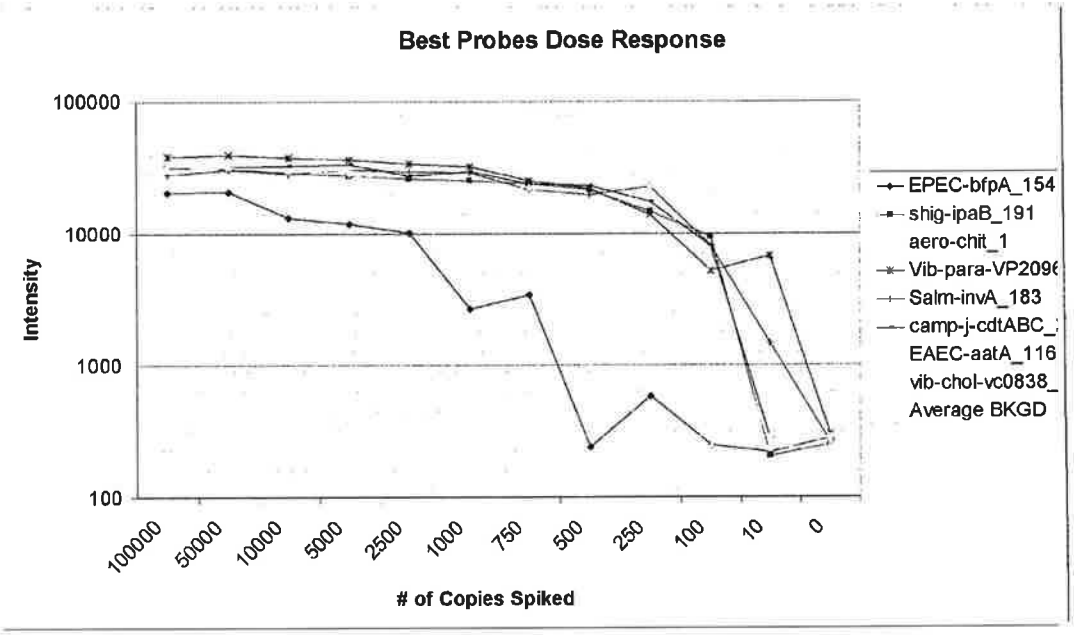
Dose-Response Graphs of Best Probes per Organism From Experiment 4



The average background of these 8 probe sets was determined from unspiked human background samples.

The results were repeatable for these probes: the range of LODs was from 10 to ~750 copies.

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Experiment 4: Dose-Response Test (Fast GoldenGate)

Organism		1	2	3	4	5	6	7	8	9	10	11	12
EPEC 2348/69	A	100000	50000	10000	5000	2500	1000	750	500	250	100	10	
Shigella-flexneri	B	100000	50000	10000	5000	2500	1000	750	500	250	100	10	
Aeromonas-gyrinophilus	C	100000	50000	10000	5000	2500	1000	750	500	250	100	10	Stool #4
Vibrio-parahaemolyticus	D	100000	50000	10000	5000	2500	1000	750	500	250	100	10	Stool #4
Salmonella-typhii	E	100000	50000	10000	5000	2500	1000	750	500	250	100	10	Stool # 5
Campylobacter-jejuni	F	100000	50000	10000	5000	2500	1000	750	500	250	100	10	Stool # 5
EAEC 042	G	100000	50000	10000	5000	2500	1000	750	500	250	100	10	BKGD only
Vibrio-cholerae 01	H	100000	50000	10000	5000	2500	1000	750	500	250	100	10	BKGD only

8 organisms were tested without human background DNA using 22 selected probes.

The number of genome copies tested ranged from 10 to 100,000.

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Benefits to Illumina

Preliminary development of microbial diagnostics platform that can be shopped to potential Dx partners

Demonstration of model where exploratory research is conducted with high multiplex Sentrix platform followed by lower multiplex/higher sample number screening is conducted on BeadXpress platform

(Very modest) revenue

Making the world better

Thanks!

Ian Lewis
Jo Yeakley
Bret Barnes
Matthew Harris
Charles Lin

David Barker
Cynthia Allred
Eliza Wickham
John Stuelpnagel
Semyon Kruglyak
Francisco Garcia
Philippe Rigault
Jian-Bing Fan

James Nataro, MD, Ph.D., University of Maryland

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